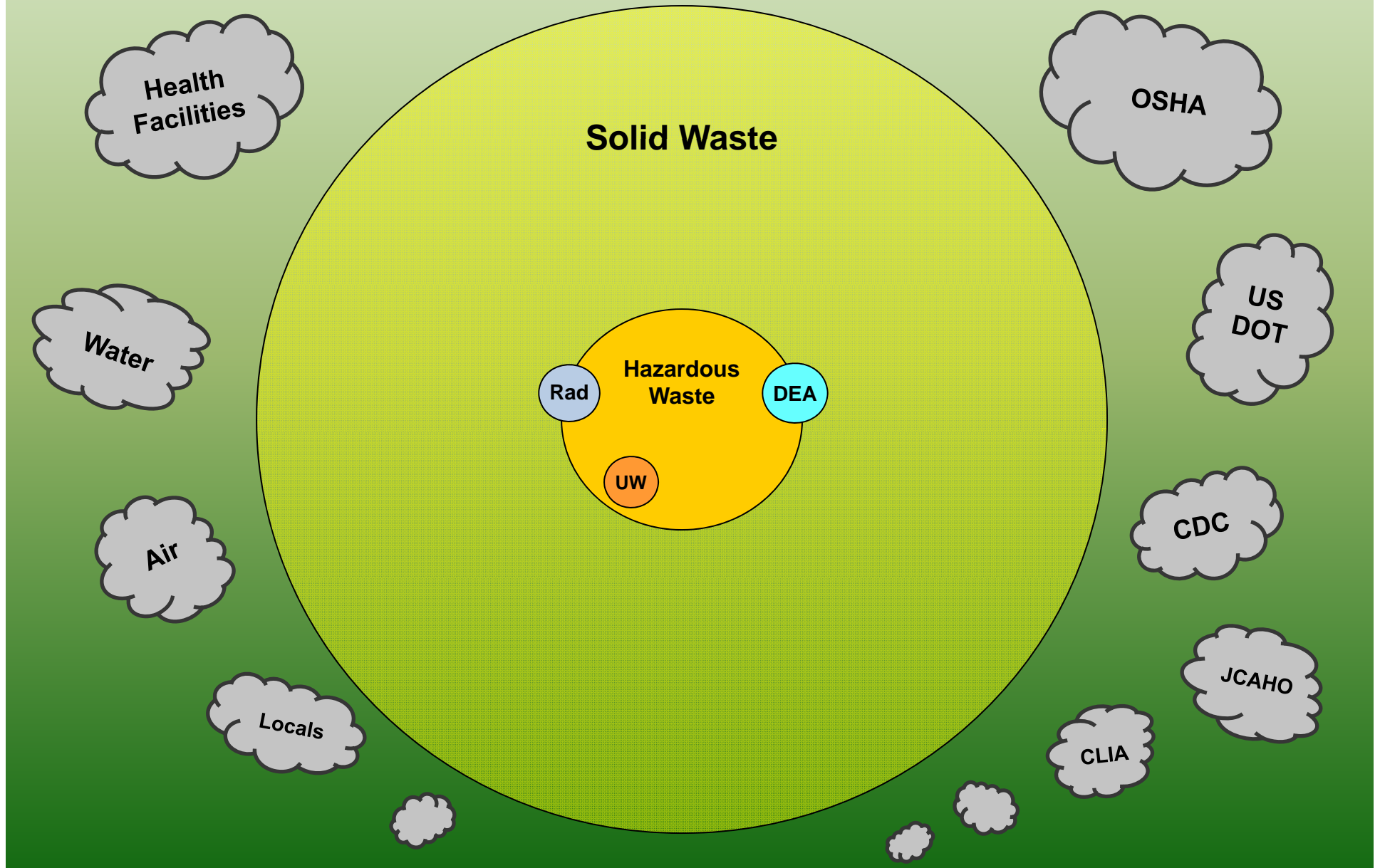


Medical Waste Generator Requirements



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Waste Universe



What is Medical Waste?

- **Any infectious, pharmaceutical or trace chemotherapy waste**
 - **Generated in a health care setting in the diagnosis, treatment, immunization or care of humans or animals**
 - **Generated in autopsy or necropsy, or during preparation of a body for final disposition**
 - **Generated in research involving biologicals or pathogens**
 - **Related to accident, suicide or other physical trauma**

Medical Waste is Not

- **Fluids, tissues or body parts**
 - Removed for the purposes of donation, research or other use
 - Returned to the person from whom they were removed as long as the material is rendered safe for handling



Medical Waste is Not

- **Medications**
 - **Donated by a patient or resident to a health care facility for reuse** [6 CCR 1011-1 Chap II, Section 7.200 et. seq.]
 - **Donated to the Cancer Drug Repository Program** [6 CCR 1015-10]
- **RCRA hazardous waste pharmaceuticals**



Medical Waste is Not

- **Lightly to moderately contaminated bandages, garments or disposable bedding**
 - Not capable of releasing liquid or caked-on blood, body fluids, tissue or other potentially infectious material during handling or storage
- **Contaminated or adulterated food or processed food items that can or have caused illness / death**



Household Medical Waste

- Household medical waste generators are exempt
 - Advised to follow best management practices
- Community collection programs must meet generator, transport and disposal requirements



Categories of Medical Waste

- **Infectious Waste**
 - Sharps
 - Blood and body fluids
 - Pathological waste
 - Potentially infectious waste
 - Other as determined by the Department
- **Non-RCRA waste pharmaceuticals and trace chemotherapy waste**

Sharps

- Any discarded article that may purposely or accidentally puncture or cut the skin or mucosa
 - Hypodermic needles and scalpel blades
 - Syringes or tubing with attached needle
 - Lancets, blood vials, suture needles
 - Culture tubes and broken culture dishes
 - Tattoo pens



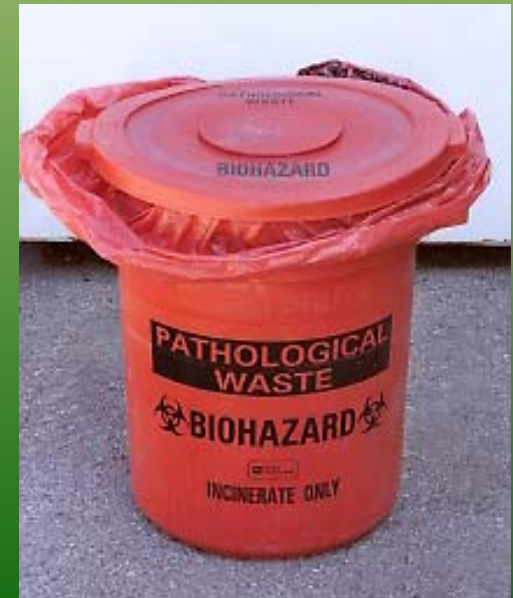
Blood and Body Fluids

- **Waste unabsorbed human and animal blood or blood products, components of blood or blood products, and other body fluids**
 - Blood, plasma, serum, platelets, pleural fluid, synovial fluid, pericardial fluid, peritoneal fluid
 - Suction and irrigation fluids
 - Liquid residues or contaminated water resulting from cleanup of medical waste spill
- **Not urine, feces, saliva, nasal secretions or vomitus unless visible blood is present**



Pathological Waste

- Tissues, organs, limbs, products of conception and other body parts removed during medical procedures
- Animal tissue exposed to infectious substances during research or contaminated with infectious substances known to be contagious to humans
 - Not animal tissue that will be composted under Section 14 of solid waste regulations



Potentially Infectious Waste

- **Wastes known or suspected to be contaminated with a transmissible infectious agent**
 - Cultures and stocks, drainage sets, dialysis wastes, IV bags and tubing containing blood (w/o needle), biohazardous waste
 - Items capable of releasing blood, body fluids or tissue in any form during handling or storage
 - Isolation wastes



Non-RCRA Pharma / Trace Chemo Waste

- **Chemical products, vaccines or allergenics intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or animals**
 - **Pills, tablets, IV solutions, vaccines, and medicinal lozenges, gums, liquids, ointments, lotions, shampoos, dermal patches**
- **Empty containers used to hold a chemo drug (except P-listed) and gowns, wipes or gloves used w/ the drug**

Radioactive Waste

- **Low level radioactive wastes**
 - Administering radiopharmaceuticals
 - Performing nuclear medicine procedures
 - Using radioactive traces in diagnostic procedures or medical research
- **Includes wastes from humans undergoing procedures such as blood contaminated waste, contaminated laboratory trash and containers used to store radioactive materials**



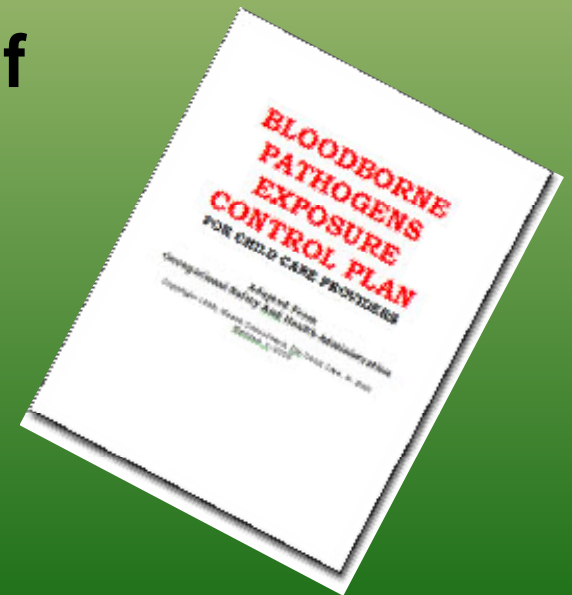
What is a Medical Waste Generator?

- **Person whose act or process produces medical waste**
 - Individuals
 - Partnerships
 - Corporations, firms, boards
- **Examples**
 - Health care facilities like hospitals, clinics, etc.
 - Flu shot clinics and health fairs
 - Funeral homes
 - Body art and acupuncture facilities



Medical Waste Management Plan

- Each generator is required to have a plan
 - Maintained at the facility
 - One for each facility
 - Specific to wastes generated
 - Not submitted to CDPHE unless requested
- OSHA / HW plans will suffice if also contain required Medical Waste Management Plan elements



Plan Components

1. Designation of medical waste
2. Provisions for the handling, treatment, and disposal of medical waste
3. Contingency plan for spills or loss of containment
4. Staff training
5. Designation of a person responsible for plan implementation

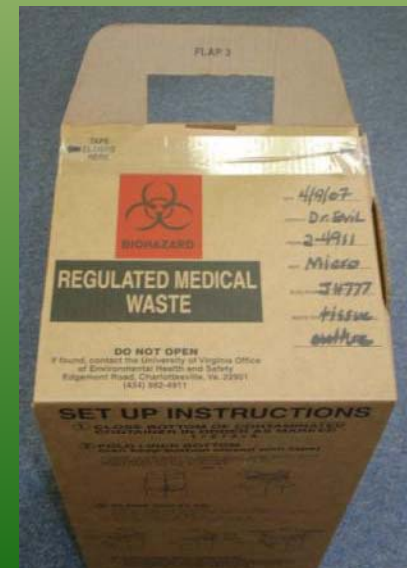


1. Designation of Medical Waste

- **Identification of the types of medical waste generated**
 - **Identify at point of generation**
 - **Medical waste, hazardous waste, radioactive waste, or ordinary solid waste**
 - **Identify where generated at facility; include community collection programs**
 - **Determine if subject to other federal, state and local statutes, regulations or policies**

2. Handling / Treatment / Disposal

- **Description of how each waste is managed**
 - Segregated, contained, packaged, labeled, transported, stored, treated and disposed
 - By category and type of treatment or disposal
 - In compliance with OSHA Bloodborne Pathogens Standard, OSHA Hazard Communication Standard and US DOT Infectious Waste requirements
 - Decay-in-storage provisions for radioactive waste
 - Alternatives in case of equipment break-down or other event



2a. Handling

- **Accumulate onsite w/o a permit if packaged to meet US DOT requirements first**
 - **Wastes containing organic matter up to 30 days**
 - **Wastes containing organic matter up to 90 days if placed in refrigeration or frozen**
 - **Sharps, pharma and trace chemo up to 90 days if container taken out of service and secured**
 - **If nuisance condition develops, must immediately refrigerate, freeze, treat or dispose**
- **Otherwise Solid Waste permit is required**

Accumulation Area

- **Inside or outside**
- **Enclosed and inaccessible to animals and pests**
- **Constructed of easily cleanable materials**
- **Secured and have warning signs to prevent unauthorized access**
- **Tracking mechanism to document compliance with accumulation time limits**

Accumulation Area

- **Inspected daily to ensure nuisance conditions don't exist**
- **Medical supplies, food and beverages should not be kept in accumulation area**



2b. Infectious Waste Treatment

- Can occur on-site or off-site
 - No permit for on-site treatment of own waste
 - Need written standard operating procedures for treatment method(s) used
 - Off-site treatment facilities must have permit
- Infectious waste must be treated to achieve at least a 99.99% reduction in certain *Bacillus* endospores and at least a 99.9999% reduction in *Mycobacterium phlei* or *bovis*
- Must demonstrate treatment effectiveness using biological indicators or parametric monitoring

2c. Disposal of Infectious Waste

- **Discharge of liquids to sewer only if in compliance with wastewater treatment plant requirements**
- **Untreated infectious waste can be disposed of in solid waste landfill only if facility is specifically approved**
 - **None currently approved**



Treated infectious waste can be disposed of as ordinary solid waste if

clearly identified as treated or must notify transporter and disposal facility



2b. Pharma / Trace Chemo Treatment

- Can occur on-site or off-site
 - No permit for on-site treatment of own waste
 - Need written standard operating procedures for treatment method(s) used
 - Off-site treatment facilities must have permit
- Can be incinerated, encapsulated, stabilized or other approved method



2c. Disposal of Pharma / Trace Chemo

- RCRA hazardous waste
- Controlled substances
 - Unopened and not dispensed can be sent to reverse distributor if they are a DEA registrant
 - Opened, dispensed and others dispose following instructions of DEA Special Agent
 - Encourage destruction
 - May allow landfilling
 - Strongly discourage disposal down drain



2c. Not RCRA, Not Controlled Substance

- **Preferred methods for untreated pharma waste**
 - **Send to a reverse distributor that ensures destruction**
 - **Use a commercial medical waste service provider that ensures destruction**
 - **Treat on-site**
 - **Treated waste can be disposed of as ordinary solid waste**
- **Trace chemo should be incinerated**

2c. Not RCRA, Not Controlled Substance

- **Untreated pharma and trace chemo waste can be disposed of in solid waste landfill only if facility is specifically approved**
 - None currently approved



3. Contingency Plan

- **Response to spill or loss of containment in order to minimize hazards**
 - Procedures to contain, cleanup and disinfect
 - Location, types and directions for use of cleanup supplies and personal protective equipment (PPE)
 - Proper disposal of used absorbents and PPE
 - Reporting requirements if release presents clear and imminent public health hazard



4. Staff Training

- **Training appropriate to job duties**
 - **Generates medical waste**
 - **Manages waste containers**
 - **Prepares waste for onsite accumulation and/or off-site transport**
 - **Treats waste onsite**
 - **Involved with recordkeeping**
- **Initial and ongoing training should be provided**

5. Person Responsible for Plan

- **Individual should have a strong knowledge of the plan and be able to communicate to other employees**
 - The importance of the plan
 - Which employees are affected by the plan
 - How to implement plan components



Recordkeeping

- **Copy of plan must be kept at the facility**
 - Should be reviewed annually
 - Must be updated whenever changes occur
- **Records related to medical waste management should be kept at the facility for at least three years**
 - Waste accumulation logs
 - Shipping papers or manifests
 - On-site treatment logs
 - Training plans and rosters



Medical Waste Generator Requirements



www.cdphe.state.co.us/hm/medicalwaste

Customer Technical Assistance Line

303-692-3320 (1-888-569-1831 ext. 3320 toll-free)

Mon – Fri 8:00 am - Noon